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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,534	11/07/2002	Danny L Serna	UCIVN-014US	4897

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,534	SERNA ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-43 are pending and under examination.

Specification

The first paragrah should contain the claim to priority. "This is a CFR 371 of ...".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 33, 34, 37, 42, 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the component "protein" in claim 33 is without support in the originally filed international application. Support exists for the recitation of human insulin or human albumin, but not for the broader concept of "protein".
plication.

Insertion of "albumin and insulin" are a broadening of the original disclosure which is limited to human albumin and human insulin.

Insertion of the term, "heparin" is a broadening of the original disclosure which is limited to the sodium salt of heparin.

ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of ***making*** and using it, in such full, clear, concise, and exact terms as to enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

The components of the inventive composition are not fully disclosed.

The concentration and exact identities of the buffers, THAM and phosphate buffer, or the final pH of the composition, which are critical or essential to the practice of the invention, but not included in the claims are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

First, the substitute specification filed 1/6/06 states on page 2 that "$NaPO_4$" in a concentration of 2.5mmol/L is present in the composition. First there is no such salt as "$NaPO_4$". The abstract of the disclosure states that the salt used is Na_3PO_4. Thus, the recitation in the specification of "$NaPO_4$" is interpreted to be in error and it is interpreted to be Na_3PO_4. Then on page 17, it is "NaH_2PO_4" in a concentration of 2.5mmol/L that is stated to be present in the composition. These two phosphate salts have very different Pka constants which produce very different pHs AT THE SAME CONCENTRATION when dissolved. Further, another buffer (THAM) is stated to be present by describing how much of an undisclosed concentration of stock solution is added to the composition. This coupled with complete absence of disclosure of the final pH of the composition renders the specification not enabled for the claimed composition. One of skill in the art cannot determine how much of either buffer and in what form the phosphate buffer (which determines the pH of the phosphate buffer in solution) should be added, especially since the final pH of the composition is not disclosed. The specification does not fully disclose the composition which is the inventive element, so

that the composition can be replicated. Therefore the specification fail to teach how to make the composition which is a neccessary element of enablement under 35 CFR 112, first paragraph.

INDEFINITE

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 recites that 7.3 cc/L Tromethamine solution is added to the composition. However, since no concentration of Tromethamine is taught in the claims or in the specification, this is an indefinite limitation.

Claim Rejections - 35 USC § 102

Claims 31-35, 37-41 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by US 6,582,953 [A].

US 6,582,953 disclose in Table 1 a solution comprising: PEG-Hb up to 20% by volume, electrolytes $MgSO_4$, KCl, $CaCl_2$, NaCl, $NaHCO_3$, NaH_2PO_4, insulin, albumin, dextrose, heparin, ascorbic acid.

Applicant argues that US 6,582,953 does not teach a hypocalcemic solution relative to the tissue of the organ being preserved. First of all, it is most likely that applicants intend to state that the solution is hypocalcemic relative to plasma or blood since the invention is a composition which is a blood substitute. The calcium ion content of an organ is rarely measured and is probably of little consequence to the instant invention. Secondly, the cited referece shows an amount of calcium chloride dihdrate of 0.265g/L. This converts to a calcium ion concentration of about 1.8mM. Remington's [U] shows a calcium concentration of 5 mEq/L in plasma. Thus, the reference cited against the claims has a "hypocalcemic" concentration relative to plasma in the described perfusion solution.

Claim Rejections - 35 USC § 103

Claims 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,582,953 [A] in view of JP 09-151134 [O] and AU 517547 [N] and/or Ebihara *et al.* [U].

The claimed composition has been discussed above and further requires lidocaine.

JP 09-151134 includes lidocaine in a solution used to perfuse organs.

The inclusion of lidocaine in the perfusate of US '953 when used for cardiac preservation, as in Example 3, would have been obvious when taken with JP 09-151134 which teaches the inclusion of lidocaine in such a solution used for cardiac transplantation.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The following rejection is applied in anticipation of the applicant's limiting the composition to human insulin and albumin.

US 6, 582, 953 includes albumin and insulin (Table 1) in the disclosed composition but do not restrict the type or source of the albumin or insulin.

AU 517547 uses human serum albumin in an organ perfusate.

The use of a human source for the generic albumin used in US '953 would have been obvious because it has been used in organ perfusates as demonstrated in AU 517547.

Ebihara *et al.* disclose that human insulin has slightly more favorable effects than porcine insulin (p. 22).

The use of a human source for the generic insulin used in US '953 would have been obvious when taken with Ebihara *et al.* because one of skill in the art may freely choose any source of insulin. Human insulin is widely available and is considered to be better than porcine insulin when used for humans

With regard to the concentrations of the components used in the claimed solution, it is note that "about" is used before the concentrations and that about permits a non-defined variation in concentrations. Thus, the concentrations used in the prior art are interpreted to fall within the claimed limits. Further, concentrations are considered to be an element of experimental design which is well within the purview of one of skill in the art and a mere optimization step in the absence of evidence to the contrary. See MPEP 2144.05 II.A.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions and/or additions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for

interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
February 17, 2006